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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/980,492

12/04/2001

Rango Dietrich

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34375 7590 03/18/2009

NATH & ASSOCIATES PLLC
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Alexandria, VA 22314

EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

03/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/980,492 | Applicant(s) DIETRICH ET AL. | |
| | Examiner Humera N. Sheikh | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 CFR §1.114, the Amendment and Applicant's Arguments/Remarks all filed 12/19/08 is acknowledged.

Applicant has overcome the following rejection(s) by virtue of the amendment to the claims and/or persuasive remarks: (1) The 35 U.S.C. §112, first paragraph rejection of claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60-62 based on the 'linear, saturated or unsaturated fatty alcohols having 10-30 carbon atoms' has been withdrawn.

Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 are pending in this action. Claims 11, 18, 41, 54, 55 & 57 have been amended. Claims 1-10, 12, 15-17, 21-32, 42, 43, 45-49, 56, 59, 61 & 62 have been cancelled. Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 are rejected.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 December 2008 has been entered.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 are rejected under 35 U.S.C. 112, first paragraph, because: (1) the specification, particularly Example 12, while being enabling for pantoprazole sodium sesquihydrate does not reasonably provide enablement and support for the group of active agents presented in instant claim 11. Claim 11, lines 7-12 recites actives generically and concludes with actives “in the form of a hydrate”. Applicant’s arguments have been considered, but were not persuasive. Specifically Applicant now directs attention to Example 12 as supporting the generic scope of the claims presented since this example does not have an amine nor polymer. Admittedly, a review of this formulation example does not have the stearylamine or the polymer suggested by the Examiner. The Examiner notes that the examples at pages 14-17, require the inclusion of a stearylamine and a polymer in addition to the fatty alcohol, and does not reasonably provide enablement for the generic “fatty alcohol” *without* inclusion of the stearylamine and polymer. However, Example 12 at page 15 establishes that the only “hydrate” that Applicants can support is the pantoprazole sodium sesquihydrate and not ‘any and all hydrates’, nor ‘any and all imidazoles’ including those that are substituted. Example 12 cannot support such a generic concept of the use of various actives in various forms. The specification Example 12 evidences that this is the only example that is capable of use in the absence of a stearylamine and polymer (i.e., povidone) and has only been shown to be used with

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pantoprazole sodium sesquihydrate, and no other active ingredient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the instantly presented claims; (2) Example 12 while being enabling for "solidified drops" is not reasonably enabled for a "microsphere" as instantly claimed herein. The term "microsphere" connotes a specific size limitation not envisioned by the words "solids" as recited in the working examples. One of ordinary skill in the art has no guidance from the instant specification as to how to formulate a microsphere using the required combinations of ingredients in suitable proportions. The subsequent formulation examples do not use pantoprazole sodium sesquihydrate in any combination in the production of a dosage delivery in microsphere form. Applicant's claims should be amended to reflect incorporation of a "pantoprazole sodium sesquihydrate" as the particular hydrate employed, in order to render the scope of the claims enabling in the absence of the recitation of a stearylamine and a polymer.

* * * * *

Response to Arguments

Applicant's arguments filed 12/19/08 have been fully considered and were found to be partially persuasive.

▪ **35 U.S.C. §112, first paragraph rejection:**

(I) Applicant argued, "Claims 11, 18, 41, 54, 55 and 57 have been amended to recite that the fatty alcohol is a linear, saturated or unsaturated primary alcohol having 10-30 carbon atoms. In view of the amendments to the claims, this rejection has been obviated."

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Applicant's arguments were found persuasive based on the amendment to the claims. Accordingly, the 35 U.S.C. §112, first paragraph rejection of claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 has been withdrawn.

(II) Applicant argued, "As discussed, and agreed upon during the interview of December 12, 2008, the specification is fully enabling for a fatty alcohol without the inclusion of a stearyl amine and polymer. In this regard, Applicants note that the specification describes a fatty alcohol without the inclusion of a stearyl amine and polymer at least at Example 12 in the specification. According to Example 12:

50 g of solid paraffin and 40 g of cetyl alcohol are fused to give a clear mixture at 100°C. The clear melt is cooled to 50-60°C. 10 g of pantoprazole sodium sesquihydrate are introduced and homogeneously suspended. The liquid suspension is prilled in the molten state in a prilling unit (Brace) having vibrating nozzles (200 µm nozzle) and the resulting drops are solidified in a cooling zone.

Applicants respectfully submit that, as is evident in example 12, according to one embodiment of the present subject matter, a solid paraffin was fused with a fatty alcohol, i.e., cetyl alcohol, to prepare a preparation according to the presently pending claims. Accordingly, Applicants submit the specification is enabling for the recitation of a fatty alcohol without the inclusion of a stearyl amine and polymer."

Applicant's arguments were not found persuasive. See detailed discussion above.

* * * * *

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

March 13, 2009

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